

## CLAIMS

What is claimed is:

1. A device for determining analyte concentrations within sample tissues, the device comprising:

an infrared radiation detector assembly;

5 an infrared transmissive window in operative combination with said infrared radiation detector assembly; and

a cooling element means for inducing a temperature gradient in said sample tissues, said cooling element means being in operative combination with said window.

2. A device as in claim 1 further including said cooling element means being in operative combination with said window and said heating element.

3. A device as in claim 2 wherein said device includes a thermal insulating element in operative combination with said cooling element means and a heating element.

4. A device as in claim 3 wherein said heating element, said cooling element means, and said thermal insulating element are each infrared transmissive elements.

5. A device as in claim 4 wherein said infrared transmissive window is a layered window and said cooling element means and said thermal insulating element each comprise a layer of said layered window.

6. A device as in claim 4 wherein said thermal insulating element comprises a layer of said layered window.

7. A device as in claim 3 wherein said heating element is selected from a group

consisting of a heat exchanger, an optical heater, an infrared heater, a radio-frequency heater, an electrical resistance heating grid, a thermoelectric heater, and a wire bridge heating grid.

8. A device as in claim 6 wherein said heating element is selected from a group consisting of a heat exchanger, an optical heater, an infrared heater, a radio-frequency heater, an electrical resistance heating grid, a thermoelectric heater, and a wire bridge heating grid.

9. A device as in claim 3 wherein said cooling element means is selected from a group consisting of a convection air cooler, a passive conduction cooler, and an active conduction cooler.

10. A device as in claim 6 wherein said cooling element means is selected from a group consisting of a convection air cooler, a passive conduction cooler, and an active conduction cooler.

11. A device as in claim 1 wherein said cooling element means for cooling induces one of a time varying temperature gradient or a periodically time varying temperature gradient.

12. A device for determining analyte concentrations within sample tissues, the device comprising in operative combination:

a layered window assembly having a plurality of infrared transmissive element means for inducing a temperature gradient in said sample tissue, said infrared transmissive element means including a heating element, a cooling element, and a thermal insulating element;

the thermal insulating element in operative combination with said heating element and said cooling element; and

an infrared radiation detector assembly.

13. A device as in claim 12 wherein said heating element comprises a heating grid.

14. A device as in claim 12 wherein said cooling element is a thermal electric cooler.
15. A device as in claim 12 wherein said cooling element further includes a heat sink.
16. A device as in claim 15 wherein said heat sink further includes a phase change material.
17. A device as in claim 12 wherein said infrared radiation detector assembly includes an optical scrambler.
18. The device of claim 12, wherein said device further includes a signal processing system for receiving and processing data from said infrared radiation detector assembly.
19. A device as in claim 12 wherein said infrared radiation detector assembly includes a radiation detector selected from the group consisting of discrete infrared band-pass filters and detectors, an interferometer, a spectrophotometer, a grating monochromator, Fabry-Perot filters, room temperature micro-bolometers, and a variable filter monochromator.
20. A device as in claim 12 wherein said radiation detector comprises a plurality of infrared band-pass filters and detectors optimized for the detection of at least one specific analyte.
21. A device as in claim 20 wherein said infrared radiation detector is optimized for the detection of glucose.
22. A device as in claim 21 wherein said plurality of discrete infrared bandpass filters include filters having bandpass wavelengths of about  $9.3\mu$  and  $9.6\mu$ .

23. A device as in claim 21 wherein said plurality of discrete infrared bandpass filters include filters having bandpass wavelengths in the range of about  $8\mu$  to  $9\mu$  and  $10\mu$  to  $11\mu$ .

24. A device as in claim 20 wherein said plurality of discrete infrared bandpass filters include filters optimized for the measurement of water, said filters having bandpass wavelengths in the range of about  $5.9\mu$  to  $6.2\mu$  and about  $11.5\mu$  to  $13\mu$ .

25. A device as in claim 20 wherein said plurality of discrete infrared bandpass filters include filters optimized for the measurement of water, said filters having bandpass wavelengths in the range of about  $10\mu$  to  $11\mu$ .

26. A device as in claim 20 wherein said plurality of discrete infrared bandpass filters include filters optimized for the measurement of proteins, said filters having bandpass wavelengths in the range of about  $6.2\mu$  to  $6.6\mu$ ,  $7.9\mu$  to  $8.1\mu$ ,  $9.1\mu$  to  $9.4\mu$ , and  $9.4\mu$  to  $9.8\mu$ .

27. A device as in claim 20 wherein said plurality of discrete infrared bandpass filters include filters optimized for the measurement of proteins, said filters having bandpass wavelengths in the range of about  $8.2\mu$  to  $8.3\mu$ .

28. A device as in claim 20 wherein said plurality of discrete infrared bandpass filters include filters optimized for the measurement of maximum tissue depth information, said filters having bandpass wavelengths in the range of about  $5.0\mu$  to  $5.5\mu$ .

29. A device as in claim 20 wherein said plurality of discrete infrared bandpass filters include filters centered at wavelengths of about  $6.1\mu$ ,  $6.9\mu$ ,  $8.5\mu$ ,  $9.3\mu$ ,  $9.7\mu$ ,  $10.4\mu$ ,  $11.0\mu$ , and  $12.5\mu$ .

30. A device as in claim 12 wherein said heating element, and cooling element, induce one of a time varying temperature gradient or a periodically time varying temperature

gradient.

31. A device for determining analyte concentrations within sample tissue by measuring sample infrared spectral emissions, said device comprising:

an infrared transmissive window assembly;

5 a heating element means and a cooling element means each being positioned for heating and cooling said sample tissue; and

an infrared radiation detector assembly positioned such that said infrared spectral emissions from said sample tissue pass through said infrared transmissive window assembly onto a detector.

32. A device as in claim 31 wherein said heating element means is part of said infrared transmissive window assembly.

33. A device as in claim 32 further comprising an infrared transmissive thermally insulating element positioned between said heating element means and said cooling element means.

34. A device as in claim 31 wherein said cooling element means further comprises a heat sink.

35. A device as in claim 31 wherein said infrared radiation detector assembly is optimized to detect only selected infrared spectral emissions from said sample tissue.

36. A device as in claim 35 wherein said selected infrared spectral emissions are optimized to detect the presence of glucose in said sample tissue.

37. A device as in claim 31 wherein said heating element means and said cooling element means induce one of a time varying temperature gradient or a periodically time varying

temperature gradient.

38. A device for determining analyte concentrations within sample tissues by measuring sample infrared spectral emissions, said device comprising:

an infrared transmissive window assembly;

5 a means for heating and cooling said sample tissues, said means being positioned to heat and cool said sample tissue; and

an infrared radiation detector assembly positioned such that said infrared spectral emissions from said sample tissue pass through said infrared transmissive window assembly onto a detector.

39. A device as in claim 38 wherein said heating and cooling means is part of said infrared transmissive window assembly.

40. A device as in claim 39 wherein said heating and cooling means further comprises a heat sink.

41. A device as in claim 40 wherein said heating and cooling means further comprises an infrared transmissive thermal insulator.

42. A device as in claim 38 wherein said infrared radiation detector assembly is optimized for the detection of glucose in said sample tissue.

43. A device as in claim 38, further comprising a signal processor for receiving and processing a signal from said detector.

44. A device as in claim 38 wherein said means for heating and cooling said sample tissues induces one of a time varying temperature gradient or a periodically time varying temperature gradient

45. A device for determining analyte concentrations within sample tissues, the device generating a thermal gradient in the tissue and measuring infrared spectra to make determinations of analyte concentration, the device comprising in operative combination:

a layered window assembly having a plurality of infrared transmissive elements;

5 a means for inducing a temperature gradient in said sample tissue, said means in operative combination with said window assembly and in thermal communication with said sample tissue; and

an infrared radiation detector assembly in operative combination with said window.

46. A device as in claim 45 wherein said means for inducing a temperature gradient induces one of a time varying temperature gradient or a periodically time varying temperature gradient.

47. A device as in claim 45 wherein said means for inducing a temperature gradient includes an infrared transmissive heating element and a cooling element.

48. A device as in claim 47 wherein said means for inducing a temperature gradient further includes an infrared transmissive thermal insulating element positioned to provide thermal insulation between said heating element and said cooling element.

49. A device as in claim 47 wherein said cooling element further includes a heat sink.

50. A device as in claim 49 wherein said heat sink further includes a phase change material.

51. A device as in claim 47, wherein said plurality of infrared transmissive elements comprising said layered window assembly includes a thermally conductive spreader layer positioned between said sample tissue and said heating element.

52. A device as in claim 51 wherein said spreader layer is formed of a float zone silicon material.

53. A device as in claim 52 wherein said spreader layer is formed of a chemical vapor deposited diamond material.

54. A device as in claim 51 wherein said spreader layer further includes a top side having a protective layer formed thereon.

55. A device as in claim 54 wherein the protective layer is formed of a material which enhances the transmission of infrared energy through said layered window.

56. A device as in claim 54 wherein the protective layer is formed of an mechanically durable wear resistant material.

57. A device as in claim 54 wherein said protective layer is formed of a diamond-like carbon material.

58. A device as in claim 54, wherein said plurality of infrared transmissive elements comprising said layered window assembly include a thermally conductive base layer positioned adjacent to said cooling element.

59. A device as in claim 58 wherein said base layer is formed of a float zone silicon material.

60. A device as in claim 58 wherein said base layer further includes a bottom side having an overcoat layer formed of a broad band anti-reflective material.



61. A device as in claim 45 wherein said infrared radiation detector assembly includes a plurality of discrete infrared bandpass filters and detectors.

62. A device as in claim 61 wherein said plurality of discrete infrared bandpass filters are chosen having bandpass wavelengths optimized to detect a specific analyte.

63. A device as in claim 61 wherein said plurality of discrete infrared bandpass filters include filters having bandpass wavelengths of about  $6.1\mu$ ,  $6.9\mu$ ,  $8.5\mu$ ,  $9.3\mu$ ,  $9.7\mu$ ,  $10.4\mu$ ,  $11.0\mu$ , and  $12.5\mu$ .

64. A device as in claim 45 wherein said infrared radiation detector assembly further comprises a high reflectance scrambler.

65. A device as in claim 45 further including a signal processing system for processing data received from said infrared radiation detector assembly.

66. An infrared transmissive patient window comprising in operative combination: a plurality of layered infrared transmissive element means for inducing a temperature gradient in said sample tissues, including a heating element and a thermal insulating element.

67. The window of claim 66, in which said plurality of layered infrared transmissive element means further includes a spreader layer and a base window.

68. The window of claim 67, wherein said spreader layer is positioned adjacent to said heating element, the heating element being adjacent to said thermal insulating element, and said thermal insulating element being positioned adjacent to said base window.

69. The window of claim 68, wherein said spreader layer includes a top surface

having a protective layer, said protective layer being formed of an infrared transmissive material which enhances the energy transmission of said window and having high thermal conductivity and having a high mechanical wear resistance.

70. The window of claim 69, wherein said base window includes a bottom surface having an overcoat layer.

71. The window of claim 66, wherein said heating element and thermal insulating element induces one of a time varying temperature gradient or a periodically time vary temperature gradient.

72. A method for making a device for generating a thermal gradient in sample tissue and measuring infrared spectra to determine analyte concentrations in said sample, the method comprising the steps of:

5 providing a layered window assembly having a plurality of infrared transmissive elements;

providing a means for inducing a temperature gradient, said means in operative combination with said window;

providing an infrared radiation detector in operative combination with said window; and

10 providing a signal processing system in operative combination with said radiation detector.

73. The method of claim 72 wherein said step of providing a layered window assembly having a plurality of infrared transmissive elements includes providing an infrared transmissive thermal insulating element.

74. The method of claim 73 wherein said step of providing a means for inducing a temperature gradient further includes the step of providing a heating element and a cooling

element with said infrared transmissive thermal insulating element disposed therebetween.

75. The method of claim 74 wherein said step of providing a layered window assembly having a plurality of infrared transmissive element means includes providing said heating element as one of said plurality of infrared transmissive elements.

76. The method of claim 75 wherein said step of providing a layered window assembly having a plurality of infrared transmissive element means includes providing a first thermally conducting infrared transmissive element, said first thermally conducting element having a top surface and a bottom surface, said top surface having an infrared transmissive protective layer being disposed thereon, said protective layer being disposed adjacent to said sample tissue.

77. The method of claim 76 wherein said step of providing said heating element as one of said plurality of infrared transmissive element means includes positioning said heating element adjacent to said bottom surface of said first thermally conducting element.

78. The method of claim 74 wherein said step of providing said heating element includes the further step of selecting said heating element from the group consisting of a heat exchanger, an optical heater, an infrared heater, a radio-frequency heater, an electrical resistance heating grid, a thermoelectric heater, and a wire bridge heating grid.

79. The method of claim 74 wherein said step of providing an infrared radiation detector in operative combination with said window includes the further step of selecting said infrared radiation detector from the group consisting of discrete infrared bandpass filters and detectors, an interferometer, a spectrophotometer, a grating monochromator, tunable Fabry-Perot filters, and a variable filter monochromator.

80. The method of claim 79 wherein said step of providing an infrared radiation detector includes the step of providing a plurality of discrete infrared bandpass filters which are interchangeable.

81. The method of claim 80 wherein said step of providing said plurality of discrete infrared bandpass filters includes providing filters having bandpass wavelengths of about  $6.1\mu$ ,  $6.9\mu$ ,  $8.5\mu$ ,  $9.3\mu$ ,  $9.7\mu$ ,  $10.4\mu$ ,  $11.0\mu$ , and  $12.5\mu$ .